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09/214,723 01/11/99 OKA

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| EXAMINER |
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| PAWUL, A |              |
| ART UNIT | PAPER NUMBER |

1656

DATE MAILED:

04/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/214,723

Applicant(s)

Takanori Oka

Examiner

Anna Pawul

Group Art Unit

1653



☒ Responsive to communication(s) filed on Jan 18, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

☒ Claim(s) 1-12 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-12 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

Amendment filed on January 18, 2000 has been entered.

***Withdrawn Rejections - 35 USC § 112***

1. The previous rejection of claims 3, under 112 2nd paragraph regarding the term “utilizing theoretical values” has been thoroughly considered and in view of applicants amendment of the claims has been withdrawn.
2. The previous rejection of claims 1-3, 7-9 under 112 2nd paragraph regarding the term “labeled standard DNA” has been thoroughly considered and in view of applicants amendment of the claims has been withdrawn.
3. The previous rejection of claim 3 under 112 2nd paragraph regarding the term “A/B” and “B/A” has been thoroughly considered and in view of applicants amendment of the claims has been withdrawn.
4. The previous rejection of claims 1, 4-10 under 35 USC 103 has been thoroughly considered and in view of applicants arguments has been withdrawn.

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***Specification***

5. The abstract of the disclosure is objected to because it is two paragraphs and over 250 words. Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 4,5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. These claims contain improper Markush language. It is suggested that it be clarified by rewriting the claim to state "is selected from *the* group consisting of".

8. Claims 1,11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language used in claims 1 & 11 appear to be literal translation. This renders the claim difficult to read because of the improper grammar and run on sentences. Please correct.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-12 rejected under 35 U.S.C. 103(a) as being unpatentable over Orion-Yhtyma Oy (WO9113075), Terouanne et al (Analytical Biochemistry, 1992) and Levi et al ( Cancer Research, 1991).

Orion-Yhtyma teaches a method that detects nucleotide variations, specifically point mutations. Orion-Yhtyma teaches that point mutations in the human ras-gene family (H-, K-, and N-ras genes) have been shown to convert them to transforming oncogenes (p.3). Orion-Yhtyma also teaches that the target nucleic acid can be any human, animal, plant cell or microbe (p.10).

Orion-Yhtyma teaches the use of primer pairs to amplify the DNA, and also complementary sequences that have a site capable of binding to a solid support (p.11). In addition, Orion-Yhtyma teaches that the "standard DNA" can be synthesized by chemical means (p.12) and that all these can be packaged in a kit (p.19).

Orion-Yhtyma does not teach the use of double-stranded DNA.

Terouanne et al teach a competitive hybridization assay. Terouanne et al teach the use of double-stranded DNA PCR products to detect variations in DNA sequences (abstract). Terouanne et al teach the use of this method to detect single base mutations (p.196). In addition, Terouanne et al teach the use of primer pairs, the use of a "standard DNA" which is detectably

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labeled and also labeled so that it can bind to a solid support (p.193). Terouanne et al also teach quantifying the bound DNA in the assay 195-196).

Terouanne et al does not specifically teach the use of this method for detecting mutations in the human ras-gene family (H-, K-, and N-ras genes), but they do teach that this method "can be a new tool for gene polymorphism studies" (p. 198).

Levi et al teach a method that utilizes a modified PCR assay to detect mutations in K-ras (abstract). Levi et al teach the use of genomic DNA, multiple primers and multiple amplification steps (p. 3498, 3502).

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Levi et al regarding a nucleic acid assay method that comprises preparing a sample nucleic acid by amplification, with the teachings of Orion-Yhtymä Oy (WO9113075) and Terouanne et al (Analytical Biochemistry, 1992) regarding the use of a method that detects nucleotide variations, specifically point mutations and a competitive hybridization assay. One of ordinary skill in the art would be motivated to produce the invention as a whole because this method "can be a new tool for gene polymorphism studies" (Terouanne et al, p. 198).

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Pawul whose telephone number is (703) 305-0806. The examiner can normally be reached Monday-Friday 7:30 AM to 4:00 PM (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be normally reached on Monday-Thursday from 8:00 AM to 5:00 PM (EST) and whose telephone number is (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to group 180 via the PTO Fax Center located in Crystal Mall 1. Papers may be submitted Monday-Friday between 8:00 AM and 4:00 PM (EST). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 fax Center number is (703) 305-3014 or (703) 308-4242.

AP  
4/24/2000



EGGERTON A. CAMPBELL  
PRIMARY EXAMINER